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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,567	05/12/2005	Jean-Francois Biegun	CAC.P0046	6534

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EXAMINER	
WOODALL, NICHOLAS W	
ART UNIT	PAPER NUMBER
3775	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,567	BIEGUN ET AL.	
	Examiner	Art Unit	
	Nicholas Woodall	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,13,15-21 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,13,15-21 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to applicant's amendment received on March 26th, 2010.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 12, 13, and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 20 appears to imply a limitation directed to the exposing of the plastic material to radiation hardens the material, i.e. ...so that after this exposition, said plastic material is hard enough to remove the part of the bone from the bone when said rasp is used.... A limitation directed to the exposure of a plastic material to radiation to harden the plastic material is not supported by the disclosure as originally filed. The specification filed on May 12th, 2005 does not disclose exposing a plastic material to radiation to strengthen the plastic material. The only reference to exposing the plastic material to radiation is on page 2 lines 29-30 and page 3 lines 1-6, which discloses the exposing the plastic material to radiation to sterilize the device, wherein trying to sterilize the device a second time, either by radiation or by an autoclave, would destroy the device. Furthermore, the

amended claims filed on June 26th, 2006 do not disclose a limitation directed to the plastic material being exposed to radiation to strengthen the plastic material. Therefore, the disclosure as originally filed does not support the limitation and the examiner is treating the limitation as new matter.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 15, 16, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Geisser (U.S. Patent 5,454,815).

Geisser discloses a device made from a plastic material including a carbon fiber reinforcing insert completely embedded within the plastic material, such as polyethylenes (column 3 lines 7-12), that come into contact with a bone to rasp the bone. The plastic material is hard enough to rasp the bone of the hip or knee and wears out after a single use (column 1 lines 29-35; column 1 lines 40-67), wherein the plastic is inherently capable deteriorating when put into an autoclave set to at least 137 degrees Celsius. The examiner would like to note that Geisser discloses the device can be made from polyethelynes, which is a specific material listed by the applicant in the specification for the body of the rasp (page 4 lines 24-25). Therefore, the device inherently has the capability of deteriorating at 137 degrees Celsius, since they are made from the same materials and the applicant provide the melting temperature range

for the materials. Also, the examiner would like to note that Geisser discloses that all rasps dull during use and that any dullness is a considerable disadvantage suggesting that all rasps wear out after a single use causing significant problems such as longer operation time and overheating (see column 1 lines 29-35). Geisser than discloses his invention directed to a single use plastic rasp that will be discarded after use to alleviate the need for sterilization and cleaning (see column 1 lines 61-64). Therefore, the examiner believes Geisser clearly discloses a device that wears out after a single use and is then discarded.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geisser (U.S. Patent 5,454,815) in view of Judd (U.S. Patent 1,396,934).

Geisser discloses the invention as claimed except for the insert being made from a metal. Geisser discloses a device made from a plastic material including a carbon fiber reinforcing insert completely embedded within the plastic material in order to reinforce the plastic material. Judd teaches a device made from a plastic material including a metallic reinforcing insert completely embedded within the plastic material in order to reinforce the plastic material. Because both Geisser and Judd teach devices comprising reinforcing inserts for plastic materials, it would have been obvious to one

having ordinary skill in the art at the time the invention was made to substitute one reinforcing insert with the other in order to achieve the predictable result of reinforcing the plastic material.

The device of Geisser and modified by Judd disclose the invention as claimed except for the insert being made from a shape memory material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Geisser as modified by Judd wherein the insert is made from a shape memory material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

8. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Geisser (U.S. Patent 5,454,815) in view of Morgan (U.S. Patent 5,910,106).

Geisser discloses the invention as claimed except for the plastic material being exposed to radiation. Morgan teaches exposing a plastic medical instrument with gamma radiation in order to sterilize the device (column 6 lines 10-12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Geisser wherein the plastic material is exposed to gamma radiation in view of Morgan in order to sterilize the device.

9. Claims 12, 13, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geisser (U.S. Patent 5,454,815) in view of Morgan (U.S. Patent 5,910,106).

Geisser discloses a method comprising the steps of providing a body made from a plastic material including a carbon fiber reinforcing insert completely embedded within the plastic material, such as polyamides (column 3 lines 7-12), that come into contact with a bone to rasp the bone, wherein the plastic is hard enough to rasp the bone and wears out after a single use (column 1 lines 29-35; column 1 lines 40-67), wherein the plastic is inherently capable deteriorating when put into an autoclave set to at least 137 degrees Celsius. Geisser fails to disclose the method further comprising the step of exposing the device to gamma or beta radiation. Morgan teaches a method comprising the step of exposing a device to gamma radiation in order to sterilize the device (column 6 lines 10-12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Geisser further comprising the step of exposing the device to gamma radiation in view of Morgan in order to sterilize the device.

Response to Arguments

Applicant's arguments filed March 26th, 2010 have been fully considered but they are not persuasive. The applicant's argument regarding the new matter rejection towards claims 12, 13, and 20 is not persuasive. The applicant argues that the language of claim 20 does not imply that the exposure to the radiation is what makes the plastic harder enough to remove bone is not persuasive. The claim states ...exposing said plastic material to beta or gamma rays, **so that after this exposition, said plastic material is hard enough to remove the part of the bone from the bone**...(emphasis added by the examiner). Therefore, the claim language is clearly implying that the exposure to the

gamma rays is causing the plastic to be hard enough to remove the bone. Furthermore, in the applicant's response files March 26th 2010 and the declaration filed on September 22nd 2009, state that the exposure of the plastic to the radiation hardens the material (see page 8 lines 8-23). Since, the applicant states that the exposure of the plastic to the radiation hardens the material to be able to remove bone then the language of claim 20 is clearly to imply this change in the plastic, which is not supported by the originally filed disclosure. The new matter rejection of claims 12, 13, and 20 is not withdrawn and appears to be proper. The applicant's argument that the Geisser reference is not capable of removing bone is not persuasive. The Geisser reference is specifically discloses as a one time use plastic rasp for the removal of bone and therefore meets the requirements structural and functional limitation of the claims. The applicant further argues that a later filed patent (U.S. Patent 6,120,508) states that the Geisser reference used by the examiner may have problems rasping harder bone (see page 9 of the applicant's arguments filed on March 26th, 2010. The applicant's argument is not persuasive. The reference is disclosed to be used with bone removal and just because the raps may have a problem with harder bone does not mean the device cannot rasp a hard bone or always has a problem with hard bone, but that the rasp may have a problem when rasping hard bone.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas Woodall/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art Unit 3775